

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES)	
INTERNATIONAL SRL)	
a corporation of Barbados,)	
)	
Plaintiff,)	C.A. No. 05-586-GMS
v.)	C.A. No. 05-730-GMS
)	C.A. No. 06-620-GMS
ANDRX PHARMACEUTICALS, LLC)	CONSOLIDATED
and ANDRX CORPORATION)	
)	
Defendants.)	

**MEMORANDUM IN SUPPORT OF ANDRX'S MOTION TO STRIKE
THE UNTIMELY EXPERT REPORT OF GERALD S. BRENNER, Ph.D.**

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More than six (6) months after the Court's deadline for expert reports on the '791 patent in this case, Biovail served an additional expert report in the form of a declaration from Gerald S. Brenner ("the New Brenner Report"). Biovail previously had submitted two reports from Dr. Brenner in accordance with the schedule. The New Brenner Report contains new opinions concerning infringement, nowhere to be found in either of his initial two reports. Moreover, none of these new Brenner opinions rebuts evidence found in Andrx's timely-served expert reports on the '791 patent.

Biovail did not seek the Court's leave to file any supplemental report. Nor did Biovail even attempt to demonstrate any reason why Dr. Brenner could not have expressed these opinions in a timely manner. There can be no dispute that the facts discussed in the New Brenner Report were known to Biovail and Dr. Brenner at the time of his first two, timely-served reports on the '791 patent

Forcing Biovail to respond to the New Brenner Report will disrupt the schedule or impose undue burden to Andrx as it simultaneously prepares expert reports for the '866 patent (due April 9th and May 9th), and prepares for trial of both patents on October 9, 2007 – a date which the Court may recall Biovail had persistently sought to delay.

I. BACKGROUND

The time for serving expert reports on the '791 patent has long passed. Initial reports were due last July, and rebuttal reports were due last September. *See* Third Revised Scheduling Order (D.I. 90). These deadlines came and went; all parties complied and benefited from the orderly disclosure of expert testimony. Indeed, Biovail served two reports by Dr. Brenner in accordance with this schedule: one regarding infringement of

the '791 patent and another regarding its validity. Except for depositions, expert discovery on the '791 patent was closed.

The addition to this case of a recently-issued patent (the '866 patent) did not reopen expert discovery on the '791 patent (though the parties did agree to delay expert depositions and set an expedited schedule for serving expert reports regarding the '866 patent). *See* Oct. 6, 2006 letter to Court (D.I. 94); Oct. 17, 2006 Order (D.I. 96); Fourth Rev. Sched. Order (D.I. 97). Trial is now set for October 9, 2007. *See* Tr. of Feb. 9, 2007 Status Conf. at 9 (Ex. A, attached hereto) (D.I. 135).

Six weeks after the '866 patent was added to this case, and over four months after the expert report deadlines, Andrx moved for summary judgment of non-infringement of the '791 patent on the grounds of collateral estoppel, arising from Biovail's failure in a prior case to prove infringement the '791 patent. (D.I. 108). To oppose Andrx's motion (and cross-move), Biovail generated and filed a "declaration".¹ This "declaration" compared the diltiazem capsule of the previous litigation to the diltiazem tablet of the present litigation. (D.I. 126-128). Later, the parties agreed to withdraw summary judgment motions. (D.I. 129).

Six weeks after that – *a full eight months after its initial expert reports were due* – Biovail purported to serve Andrx with a "supplement" to Dr. Brenner's

¹ (D.I. 126-128). Before filing its opposition, Biovail moved for an extension of time, indicating that it needed time to consult with Dr. Brenner regarding the similarities between the accused product in this case and the accused product in the prior case. (D.I. 112). Andrx opposed this motion, noting that Biovail was attempting to evade long-established expert discovery deadlines. (D.I. 113). While the motions were pending, the case was reassigned to Judge Sleet, who granted the extension based solely on the fact that because the case had just been assigned to him, he would give Biovail "the benefit of the doubt." (D.I. 120). The Order did not address the impropriety of the Brenner "declaration", which, of course, had yet to be filed.

original infringement report from the Summer of 2006; this “supplement” purports to incorporate by reference Dr. Brenner’s withdrawn “declaration.” *See* Ex. B, attached hereto.

II. ARGUMENT

This Court may strike expert reports that are not timely served in accordance with scheduling orders. Fed. R. Civ. P. 26(a)(2) and 37(c)(1). This Court, along with others in this circuit, have frequently stricken untimely expert reports in cases involving sophisticated litigants. *See, e.g., Cuffee v. Dover Wipes Co.*, 334 F. Supp. 2d 565, 572 (D. Del. 2004); *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 463 (D. Del. 2003); *In re Safeguard Scientifics*, C.A. No. 01-3208, 2004 U.S. Dist. LEXIS 23494 at *4-5 (D. Del. Nov. 17, 2004) (Ex. C attached hereto); *Union Carbide Chems. & Plastic Tech. Corp. v. Shell Oil Co.*, 270 F. Supp 2d 519, 524 (D. Del. 2003); *Stein v. Foamex Int’l, Inc.*, No. 00-2356, 2001 U.S. Dist LEXIS 12211, at *19 (E.D. Pa. Aug. 15, 2001) (Ex. D attached hereto); *Astrazeneca v. Mutual Pharm. Co., Inc.*, 278 F. Supp. 2d 491, 504, 508-09 (E.D. Pa. 2003).²

Indeed, this Court has recognized that “sometimes . . . exclusion is necessary; fidelity to the constraints of Scheduling Orders and deadlines is crucial to the Court’s case management responsibilities [and] flouting of discovery deadlines causes substantial harm to the judicial system.” *Praxair*, 231 F.R.D. at 463 (quoting *Finch v. Hercules, Inc.*, 1995 U.S. Dist. LEXIS 19805 (D. Del. 1995)).

² Although in civil rights cases involving individual plaintiffs the Third Circuit has recognized preclusion as a harsh measure, “Courts . . . need not be so indulgent in patent cases . . . involving two large business entities, with expertise in their respective fields, and with highly competent counsel representing them.” *Astrazeneca v. Mutual Pharmaceutical Co., Inc.*, 278 F. Supp. 2d 491, 504, 508-09 (E.D. Pa. 2003).

In determining whether to grant a motion to strike an untimely expert report, this Court should consider the prejudice and disruption that would result from allowing the report, as well as the bad faith or willfulness of the delinquent party. *Stein*, No. 00-2356, 2001 U.S. Dist LEXIS 12211 at *8-9 (citing *In re Paoli Railroad Yard PCB*, 25 F.3d 717, 791-793 (3d Cir. 1994). This Court has, however, stricken untimely reports where the party simply “dropped the ball” and there was no evidence of intentional non-disclosure or bad faith. *Cuffee*, 334 F. Supp. 2d at 570, 572 (reports stricken because party failed to serve them until 14 weeks after the deadline set in the scheduling order, and only five months before trial). Even where a trial date has not yet been set, and there is no bad faith, the Court may strike untimely expert reports if the delay is not justified. *See Astrazeneca*, 278 F. Supp. 2d at 508, 510.

Here, the circumstances suggest that Biovail knowingly violated the scheduling order in a post-hoc, bad faith attempt to shore up its insufficient expert proofs.

First, Biovail’s violation was knowing and willful. Biovail knew that it had failed in a prior case to prove that Andrx’s earlier version of a diltiazem product infringed the ‘791 patent. *Biovail Corp. v. Andrx Pharms., Inc.*, 158 F. Supp. 2d 1318 (S.D. Fla. 2000), *aff’d* 239 F.3d 1297 (Fed. Cir. 2001). In the prior case, the Federal Circuit affirmed the finding of no infringement because – even under Biovail’s proposed claim construction – Biovail had not proved that the “beads” of the accused diltiazem capsule product formed a “homogeneous admixture” *in vivo*. *Biovail*, 239 F.3d at 1303. In the present case, Biovail asserted the same claim construction as before, and quickly learned that Andrx’s new diltiazem tablet product employs precisely the same “beads” as the old product. Thus, Biovail had an obvious incentive to develop expert testimony

regarding any differences between the beads used in the two diltiazem products, to counter a collateral estoppel defense. *C.f. Union Carbide Chems. & Plastic Tech. Corp. v. Shell Oil Co.*, 270 F. Supp 2d 519, 523-24 (D. Del. 2003) (granting motion to strike where defendant failed to develop expert testimony to address plaintiff's claim construction; then after the Federal Circuit adopted plaintiff's claim construction, defendant attempted to serve new expert reports in light of plaintiff's (now binding) claim construction). In short, Biovail consciously chose not to produce an expert report concerning its infringement theory. *See, e.g., Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 463 (D. Del. 2003) (striking untimely expert report in part because the delinquent party should have recognized the issue months before the expert report deadline).

Second, Biovail has been far from candid in its attempts to present the New Brenner Report. Only after Andrx's summary judgment motion highlighted the insufficiency of Biovail's expert evidence did Biovail even begin to consult Dr. Brenner on this issue. Then, rather than seek leave to serve this new report, Biovail instead, styled it as a "declaration" and attached it to its summary judgment brief. (D.I. 126-128). These facts alone suggest that the report has been presented in bad faith. *See In re Safeguard Scientifics*, C.A. No. 01-3208, 2004 U.S. Dist. LEXIS 23494 at *14-15 (D. Del. Nov. 17, 2004); *Stein v. Foamex Int'l, Inc.*, No. 00-2356, 2001 U.S. Dist LEXIS 12211 at *18-19 (E.D. Pa. Aug. 15, 2001) (finding that expert report was presented in bad faith where delinquent party filed an affidavit in opposition to a summary judgment motion rather than formally supplementing).

But Biovail's lack of candor did not stop there. A month after the parties agreed to withdraw their cross-motions for summary judgment, Biovail purported to

“supplement” Dr. Brenner’s original report under Rule 26(e)(1) by incorporating by reference Dr. Brenner’s withdrawn “declaration.” Ex. B. But Dr. Brenner’s “declaration” is not a supplementation. It is not offered to correct any incomplete or incorrect portions of Dr. Brenner’s original report; rather it offers new opinions on new subject matter, comparing the beads of diltiazem capsule with the beads of the diltiazem tablet. Fed. R. Civ. P. 26(e)(1); *see Stein*, 2001 U.S. Dist. LEXIS at *15. This is further evidence that Biovail has presented the new Brenner Report in bad faith.

Third, allowing the new Brenner report to stand will disrupt the current schedule. In fact it already has: Biovail delayed the summary judgment briefing for five weeks to generate the New Brenner Report. (D.I. 112, 113, 120). If the new report is not stricken, Andrx will have to carve out time and resources from the discovery schedule set for the ‘866 patent to deal with the New Brenner Report.

Fourth, even though Dr. Brenner has not yet been deposed, the opportunity to conduct more costly expert discovery at this stage is not an adequate cure. *See, e.g., Praxair*, 231 F.R.D. at 463 (“while the prejudice may be cured by allowing plaintiffs additional expert discovery, this would undoubtedly disrupt the trial process, as trial is set to begin in less than a month.”); *Astrazeneca v. Mutual Pharm. Co., Inc.*, 278 F. Supp. 2d 491, 504, 507 (E.D. Pa. 2003) (declining to allow additional discovery because “the Court concludes that such a procedure would not only reward Defendant’s multiple violations of pretrial procedures, but would also not be fair to Plaintiffs, and would, further, seriously delay any resolution of this litigation”). This Court should strike the New Brenner Report to prevent the very disruption that its scheduling orders are meant to prevent.

III. CONCLUSION

For the foregoing reasons, Andrx respectfully requests that this Court strike (1) the "Declaration of Gerald S. Brenner" filed in support of Plaintiff Biovail Laboratories International SRL's ("Biovail's") January 19, 2007 opposition to summary judgment (and in support of its cross motion for summary judgment), and (2) the March 7 "Supplement to the Expert report of Gerald S. Brenner", served by Biovail.

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CERTIFICATE OF SERVICE

I, Kenneth L. Dorsney, hereby certify that on April 11, 2007, the attached document was hand-delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF.

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